



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/520,414

01/06/2005

Raju Adhikari

23292.0003U1

5460

23859

7590

05/14/2008

NEEDLE & ROSENBERG, P.C.

SUITE 1000

999 PEACHTREE STREET

ATLANTA, GA 30309-3915

EXAMINER

DICKINSON, PAUL W

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

05/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,414

Applicant(s)

ADHIKARI ET AL.

Examiner

PAUL DICKINSON

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 13, 15-18 and 23-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 12, 14 and 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's arguments, filed 2/29/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicant states that Claims 29-32, which were added by amendment on 1/6/2005, properly belong in Group II (the elected Group). These claims were overlooked by the Examiner in the restriction requirement mailed 9/12/2007 and were not mentioned in the response to the restriction requirement filed 10/12/2007. The Examiner agrees with Applicant that Claims 29-32 properly belong in Group II. Applicant states, and the Examiner agrees, that these claims do not read on the elected species.

. Claims 1-38 are pending. Claims 11, 22 and 26 have been amended. Claims 33-38 are new. Claims 11, 12, 14, and 19-22 read on the elected species and are currently under consideration.

Response to Arguments

Claim Rejections - 35 USC § 102

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by EP 0837084 (hereafter '084) for the reasons set forth in the previous office action.

Applicant argues that Claim 11 is distinguishable from '084 because it recites isocyanate reacted directly with a multifunctional core molecule, whereas '084 discloses that the isocyanate is reacted with a polymer or copolymer formed from the reaction between a core molecule and further monomers. In the instant claims, the urethane linkages formed through the reaction of isocyanate with the core molecule are close to the core as illustrated by Scheme 1 of the present application. In contrast, in '084 the isocyanate is used to end-cap a polymer or copolymer.

Applicant's arguments have been fully considered but are not found persuasive. The features upon which applicant relies are not recited in the rejected claim. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Instant Claim 11 requires a composition comprising the reaction product of a flowable prepolymer and linear star dendrimer or hyperbranched soft segment forming functional oligomers with degradable arms, wherein the prepolymer comprises the reaction product of an isocyanate and a low molecular weight multifunctional core molecule having at least two functional groups that react with said isocyanate to form urethane or urea groups. Comparing the composition disclosed by '084 to the instant claim, lysine isocyanate ('084) corresponds to the isocyanate (Instant Claim 11), the star copolymer formed by reaction of p-dioxanone, glycolide, and pentaerythritol ('084) corresponds to the low molecular weight multifunctional core (Instant Claim 11). The reaction product of the isocyanate and the above star copolymer ('084) corresponds to the prepolymer (Instant Claim 11), and this prepolymer

is treated with poly(ethylene oxide monomethyl ether) ('084), which corresponds to the hyperbranched soft segment (Instant Claim 11). Therefore, the isocyanate disclosed by '084 is reacted directly with a low molecular weight multifunctional core, that core being a star copolymer formed by reaction of p-dioxanone, glycolide, and pentaerythritol. There is nothing disclosed in the instant claims or specification that limits "low molecular weight multifunctional core" in such a way to make a distinction from '084.

The rejection of Claim 11 under 35 U.S.C. 102(b) as being anticipated by '084 is maintained.

Claim Rejections - 35 USC § 103

Claims 12, 14, and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0837084 (hereafter '084) in view of US 3281378 (hereafter '378) for the reasons set forth in the previous office action.

Applicant argues that the disclosure of '084 does not destroy the novelty of the present claims for the reasons set forth above. Additionally, the reference is silent with respect to flowable and injectable compositions, the major advantage of the compositions of the instant invention. Furthermore, the reactions exemplified by '378 are carried out in toxic organic solvents, which indicates a teaching away from *in vivo* administration of the composition in the absence of solvent. There is no teaching in '378 that the products are injectable or flowable in the absence of solvent. There is therefore no teaching in '378 that would lead the skilled artisan to eliminate the solvents with any expectation of achieving the product flowability recited in the claims.

Applicant's arguments have been fully considered but are not found persuasive. The Examiner agrees that neither reference uses the word "flowable" or "injectable". A composition cannot be separated from its properties, and the composition formed by combining the disclosure of '084 and '829 for the reasons set forth in the previous office action, must have these properties. See § MPEP 2112, I.

Regarding Applicant's arguments that '378 teaches away from *in vivo* administration of the composition in the absence of solvent, firstly, the disclosure of preferred embodiments does not constitute a teaching away from nonpreferred embodiments. Secondly, '084 teaches the utility of the disclosed compositions as suitable *in vivo* implants, in the absence of solvent. Lastly, the instant claims are only obvious over the combination of the above references. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The rejection of Claims 12, 14, and 19-22 under 35 U.S.C. 103(a) as being unpatentable over '084 in view of '378 is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

May 6, 2008